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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,068	04/14/2004	Chih-Ping Liu	55600-8014.US03	7994

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/825,068	**Applicant(s)** LIU ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,4,6,8,10 and 11*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Continuation of 13. Other: Claims 1, 3-4, 6, 8, and 10-11 remain rejected under 35 U.S.C. 112, first paragrph, for lack of enablement for a method of increasing the IL-10/IL-12 blood ratio, or of inhibiting progression of multiple sclerosis, comprising administering any polypeptide that is less than 100% identical to the polypeptide of SEQ ID NO: 2. In the response received on 8/27/2007, the Applicants argue that the claims have been amended to read on administering an IFN-tau polyppetide having at least 90% sequence homology to SEQ ID NO: 9, wherein said polypeptide does not contain substitutions or alterations that significally effect activity, and therefore the claims are limited to only IFN-tau polypeptides with the desired biological activities. The Applicants further argue that the specification provides examples of various IFN-tau polypeptides, and one of ordinary skill in the art would be able to determine whether or not an IFN-tau polypeptide retained the desired activity. These arguments have been fully considered and are not pesuasive. Altough the claim amendments have narrowed the breadth of the claims, the specificaiton does not provide guidance showing how to make and then use all possible IFN-tau polypeptides that are less than 100% identical to SEQ ID NO: 2. The specification does not provide guidance concerning which residues/regions of SEQ ID NO: 2 can be altered or substituted, and thus a skilled artisan would not be able to make all possible IFN-tau polypeptides having less than 90% homology to SEQ ID NO: 2 without further experimentation. Furthermore, because a skilled artisan would recognize the unpredictability inherent in the effects of alteration or substitution of amino acids within a given polypeptide, one of skill in the art would not necessarily predict that the claimed IFN-tau polypeptides would all be capable of inhibiting progression of multiple sclerosis or increasing the IL-10/IL-12 blood ratio in a subject.

Similarly, the specification does not provide adequate written description for the claimed genus of IFN-tau polypeptides having less than 100% identity ot SEQ ID NO: 2 and still retaining the desired activities. The Applicants argue that the amendments to the claims to recite IFN-t polypetpides that are at least 90% identical to SEQ ID NO: 2, with the limitation that said IFN-tau polypeptides do not contain substitutions or alterations that significally effect activity, combined with the examples in the specification of various IFN-tau polypeptides provides adequate written description for the claimed genus of IFN-tau polypeptides. These arguments have been fully considered and are not persuasive. It is noted that, with the exception of SEQ ID NO: 3, it is not clear which of the IFN-tau polypeptides recited in paragraph 0036 are at least 90% identical to SEQ ID NO: 2. Furthermore, there is no description of which regions or domains or residues of SEQ ID NO: 2 can be substituted or altered in order to create an IFN-tau polypeptide with activity. There is no structure/function relationship presented that would allow one to determine which amino acids/regions can be altered. Therefore, with the exception of the polypeptide of SEQ ID NO: 3, which by itself is insufficient to describe the claimed genus, the specification does not describe which polypeptides having less than 100% identity to SEQ ID NO 2 are actually IFN-t polypeptides with activity.

Claims 1, 3-4, 6, 8, and 10-11 remain rejected under 35 U.S.C. 103(a) as being obvious over the combination of Soos et al, van Boxel-Dezaire et al, and Petereit et al. In the response received on 8/27/2007, the Applicants argue that the claims of the instant invention are not obvious in view of the recited combination of art because each and every claim limitation has not be identified in the prior art, specifically with regards to the claimed dosage of IFN-tau. Furthermore, the Applicants argue that the claimed method and dosage of IFN-tau adminstration provides superior results compared to the prior art which was unexpected, and therefore the claims cannot be obvious. These results have been fully considered and are not persuasive. It is noted that the declaration of Dr. Norman Kachuck describes administration of IFN-tau at only one dose. Thus, it is not clear that the claimed dosage would provide superior results compared to lower dosages. It is also not clear that the increased serum IL-10 levels observed after administration of the claimed IFN-tau dose, as described in Fig. 4D, would truly be unexpected because it is known in the art that administering a higher dose of a given compound may increase the effectiveness of said compound. Therefore, because the art teaches the general conditions of the claims, namely administration of IFN-tau for the treatment of multiple sclerosis, it would be obvious to one of ordinary skill in the art to optimize the dosage of IFN-tau for treatment of multiple sclerosis, and it would also be obvious to one of oridnary skill in the art that the administered IFN-tau would increase the IL-10/IL-12 blood ratio because Soos shows increased production of IL-10 in response to IFN-tau.

Claims 1, 3-4, 6, 8, and 10-11 remain rejected under the judicially created doctorine of obviousness-type double patenting as being unpatentable over claims 1, 17, and 18 of co-pending Applicantion 11/112,369. Applicant's submission of a termianl disclaimer is noted. Upon approval of said terminal disclaimer, the rejection will be withdrawn.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner , Art Unit 1647